UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
07/422,699	10/17/89	RUEGER D	CRP001CP3

LAHIVE AND COCKFIELD
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BOSTON, MA 02109

EXAMINER	
NUTTER, N.	
ART UNIT	PAPER NUMBER
153	8

DATE MAILED: 04/20/90

This is a communication from the examiner in charge of your application.

COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 29 Jan 1990 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~days~~ from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449, 3.
4. ☐ Notice of Informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1 - 27 are pending in the application.

   Of the above, claims 14-20 and 22-27 are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 1-13 and 21 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☒ This application has been filed with informal drawings which are acceptable for examination purposes until such time as allowable subject matter is indicated. Note PTO-948, acknowledged with Paper No. 2.

8. ☐ Allowable subject matter having been indicated, formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. These drawings are ☐ acceptable; ☐ not acceptable (see explanation).

10. ☐ The ☐ proposed drawing correction and/or the ☐ proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved. ☐ disapproved (see explanation). However, the Patent and Trademark Office no longer makes drawing changes. It is now applicant's responsibility to ensure that the drawings are corrected. Corrections MUST be effected in accordance with the instructions set forth on the attached letter "INFORMATION ON HOW TO EFFECT DRAWING CHANGES", PTO-1474.

12. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

Applicant's election of Group I in Paper No. 3 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP 818.03(a)).

The election of species is modified to include osteogenic proteins of the groups

1) OPS
2) OP7
3) OPM and
4) OPP, as one grouping.

However since the following groups are different, they are held to be distinct inventions and prosecution of claims drawn to them, on the merits is not included herewith.

They are:

5) CPMP2AS,
6) CBMP2AL,
7) CBMP2AM,
8) CBMP2BS,
9) CBMP2BL, and
10) CBMP2BM.

Thus, only claims 1-13 and 21 will be deemed to read on species elected, and only these claims will be prosecuted on the merits in this Office Action. Claim 21, further, is deemed to be a linking claim generic to

Group I and Group II. Claim 21 recites a "protein expressed from the DNA of claim 20", but no particulars as to sequence are given.

Claims 1-13 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are deemed to be vague and confusing since only one of the proteins of the dimeric pairs is provided. Further, in claims 3, 12 and 13 the "starred residues", which term is not art-recognized, are many and intended cleavage cites cannot be clearly ascertained. The recitation as to cleavage is absent from claims 11 and 12. Claim 21 recites a protein without giving any intended aspects of that protein for which one of ordinary skill would know which protein is intended. None of the claims recite any characteristics of the sequence given or it's supposed dimeric pair as to enable one of ordinary skill in the art to make and/or use the protein or the pair. Note the patent to Hao et al. The claims therein recite molecular weights, elution values and characteristics. These are absent from the instant claims.

Further, what is the intended scope of the matrix involved? Nothing is recited in the claims which would enable one of ordinary skill to practice and/or or produce such a matrix.

Claims 1-13 and 21 are rejected under 35 U.S.C. 103 as being unpatentable over Urist ('256) or Nathan et al ('350) taken in view of Wang et al (WO 88/00205).

The patents to Urist and Nathan et al both teach isolation of bone morphogenetic proteins which are deemed to embrace those of the instant claims with possibly only minor differences from those proteins recited in the instant claims. Note the isolation in Urist at column 3 (line 61) to column 4 (line 65). Note the protein isolation in Nathan et al at column 5 (line 27) to column 6 (line 46) and the many Examples. No side-by-side comparison has been shown on the record.

The patent to Wang et al teaches the conventionality of recombinant techniques to produce proteins possessing osteogenic capabilities as is disclosed in the instant specification. Manipulation of the products as resulting from these techniques is known in the art and is taught by the reference. Note the many possibilities obtained by the Wang et al reference as shown by the sequences of Tables II, III, IV .A., IV .B., V, VI, VII and VIII. Table VIII, in particular shows a sequence beginning with nucleotide 1326 et seq which closely corresponds but is not identical, to that recited in the instant claims. These variations are known as possible manipulations and are shown by Wang et al.

The instant claims are drawn to proteins/polypeptides, per se. Derivation of these proteins/polypeptides are irrelevant since the claims are drawn to the product, per se. Nothing on the record indicates any substantial patentable differences thereover. Thus, at the time the invention (protein/polypeptide) was made, the claimed composition would have been obvious to one having an ordinary skill in the art. There is nothing on the record to indicate otherwise.

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703-557-6525
4/16/90
4/18/90

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PATENT EXAMINER
ART UNIT 153